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IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., and Takeda Global Research and Development Center, Inc., Plaintiffs, v. Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc., Defendants.	Civil Action No.: 09-cv-4665

TEVA PHARMACEUTICAL INDUSTRIES LTD. AND TEVA PHARMACEUTICALS USA, INC.'S ANSWER AND AFFIRMATIVE DEFENSES

Defendants Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and Teva Pharmaceuticals USA, Inc. ("Teva USA"; collectively, "Teva"), by and through their undersigned attorneys, respond to the numbered paragraphs of the Complaint filed by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., and Takeda Global Research and Development Center, Inc. (collectively, "Takeda") as follows:

Jurisdiction and Venue

1. Teva admits that this action purports to be an action for patent infringement arising under the patent laws of the United States. Teva further admits that this Court has subject matter jurisdiction. Teva USA does not contest, for purposes of this litigation only, that it is subject to personal jurisdiction in this District and that venue is proper in this District. Teva Ltd. does not contest, for purposes of this litigation only, that it is subject to personal jurisdiction in this District and that venue is proper in this District. Except as expressly admitted above, Teva denies the allegations in Paragraph 1.

Parties

2. Teva is without information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies them.

3. Teva admits that ACTOS® drug products contain the active ingredient pioglitazone hydrochloride. Teva further admits that ACTOPLUS MET® drug products contain the active ingredients pioglitazone hydrochloride and metformin hydrochloride. Teva is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3, and therefore denies them.

4. Teva admits that Teva USA is incorporated in the state of Delaware and has a place of business in North Wales, Pennsylvania. Teva further admits that ANDA No. 91-155 was filed

under the name of Teva USA. Except as expressly admitted above, Teva denies the allegations in Paragraph 4.

5. Teva admits that Teva Ltd. is a corporation incorporated under the laws of Israel and has its corporate headquarters in Israel. Teva further admits that Teva USA is an indirect wholly owned subsidiary of Teva Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 5.

6. Teva USA does not contest, for purposes of this litigation only, that it is subject to personal jurisdiction in this District and that venue is proper in this District. Teva Ltd. does not contest, for purposes of this litigation only, that it is subject to personal jurisdiction in this District and that venue is proper in this District. Teva admits that Teva USA is registered with the N.Y. Department of State, Division of Corporations, to do business as a foreign corporation in New York. Except as expressly admitted above, Teva denies the allegations in Paragraph 6.

The New Drug Applications

7. Upon information and belief, Teva admits the allegations in Paragraph 7.

8. Upon information and belief, Teva admits that the approved indications for ACTOS® drug products are set forth in the FDA-approved labeling for such drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 8.

9. Upon information and belief, Teva admits that the approval letter for ACTOS®, with approved labeling, was issued by the FDA on July 15, 1999. Upon information and belief, Teva further admits that the approved indications for ACTOS® drug products are set forth in the FDA-approved labeling for such drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 9.

10. Upon information and belief, Teva admits the allegations in Paragraph 10.

11. Upon information and belief, Teva admits that the approved indications for ACTOPLUS MET® drug products are set forth in the FDA-approved labeling for such drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 11.

12. Upon information and belief, Teva admits the allegations in Paragraph 12.

The Patents in Suit

13. United States Patent No. 5,965,584 ("the '584 patent") speaks for itself. Teva admits that the '584 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of October 12, 1999 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '584 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '584 patent is attached to the Complaint as Exhibit A. To the extent Paragraph 13 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 13.

14. Upon information and belief, Teva admits that the '584 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '584 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 14.

15. United States Patent No. 6,329,404 ("the '404 patent") speaks for itself. Teva admits that the '404 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of December 11, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '404 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '404 patent is attached to the Complaint as Exhibit B. To the

extent Paragraph 15 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 15.

16. Upon information and belief, Teva admits that the '404 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '404 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 16.

17. United States Patent No. 6,166,043 ("the '043 patent") speaks for itself. Teva admits that the '043 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of December 26, 2000 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '043 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '043 patent is attached to the Complaint as Exhibit C. To the extent Paragraph 17 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 17.

18. Upon information and belief, Teva admits that the '043 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '043 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 18.

19. United States Patent No. 6,172,090 ("the '090 patent") speaks for itself. Teva admits that the '090 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of January 9, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '090 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that

what purports to be a copy of the '090 patent is attached to the Complaint as Exhibit D. To the extent Paragraph 19 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 19.

20. Upon information and belief, Teva admits that the '090 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '090 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 20.

21. United States Patent No. 6,211,205 ("the '205 patent") speaks for itself. Teva admits that the '205 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of April 3, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '205 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '205 patent is attached to the Complaint as Exhibit E. To the extent Paragraph 21 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 21.

22. Upon information and belief, Teva admits that the '205 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '205 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 22.

23. United States Patent No. 6,271,243 ("the '243 patent") speaks for itself. Teva admits that the '243 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of August 7, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '243 patent lists

on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '243 patent is attached to the Complaint as Exhibit F. To the extent Paragraph 23 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 23.

24. Upon information and belief, Teva admits that the '243 patent, if valid and enforceable, expires on June 19, 2016. Teva further admits that the '243 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 24.

25. United States Patent No. 6,303,640 ("the '640 patent") speaks for itself. Teva admits that the '640 patent, entitled "Pharmaceutical Composition," lists on its face an issue date of October 16, 2001 and lists on its face as inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, but specifically denies that the patent was duly issued. Teva further admits that the '243 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Teva further admits that what purports to be a copy of the '640 patent is attached to the Complaint as Exhibit G. To the extent Paragraph 25 states conclusions of law, no response is required. Except as expressly admitted above, Teva denies the allegations in Paragraph 25.

26. Upon information and belief, Teva admits that the '640 patent, if valid and enforceable, expires on August 9, 2016. Teva further admits that the '243 patent lists on its face as an assignee Takeda Chemical Industries, Ltd. Except as expressly admitted above, Teva denies the allegations in Paragraph 26.

27. Teva is without information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 27, and therefore denies them.

28. Upon information and belief, Teva admits that plaintiff TPNA sells pioglitazone-containing drug products under the trade name ACTOS® in the United States. Upon information and belief, Teva further admits that sales of ACTOS® are made pursuant to approval by the FDA of NDA No. 21-073. Except as expressly admitted above, Teva denies the allegations in Paragraph 28.

29. Teva is without information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 29, and therefore denies them.

30. Upon information and belief, Teva admits that plaintiff TPNA sells drug products containing a combination of pioglitazone and metformin under the trade name ACTOPLUS MET® in the United States. Upon information and belief, Teva further admits that sales of ACTOPLUS MET® are made pursuant to approval by the FDA of NDA No. 21-842. Except as expressly admitted above, Teva denies the allegations in Paragraph 30.

31. Upon information and belief, Teva admits the allegations in Paragraph 31.

32. Teva is without information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 32, and therefore denies them.

33. Teva denies the allegations in Paragraph 33.

I. TEVA's ANDA No. 91-155

COUNT I

(DIRECT INFRINGEMENT OF THE '584 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

34. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-33.

35. Teva admits that Teva USA filed ANDA No. 91-155 with the FDA under 21 U.S.C. § 355(j), seeking approval to market (i) combination Pioglitazone Hydrochloride and Metformin

Hydrochloride Tablets, Eq. to 15 mg base/500 mg, and (ii) combination Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, Eq. to 15 mg base/850 mg. Except as expressly admitted above, Teva denies the allegations in Paragraph 35.

36. Upon information and belief, Teva USA admits that its combination pioglitazone and metformin drug products will be AB rated to Takeda's combination pioglitazone and metformin drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 36.

37. Teva admits that Teva USA's Notice Letter states that it submitted to the FDA ANDA No. 91-155 "which seeks approval to engage in the commercial manufacture, use, or sale of Pioglitazone Hydrochloride and Metformin Hydrochloride, Eq. to 15 mg base/500 mg and Eq. to 15 mg base/850 mg, prior to the expiration of the '584, '042, '043, and '090 patents." Except as expressly admitted above, Teva denies the allegations in Paragraph 37.

38. Teva admits that, by a letter dated April 14, 2009, Teva USA informed Takeda that Teva USA had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Teva admits the remaining allegations in Paragraph 38.

39. Teva admits that the Notice Letter provides Teva USA's notification of certification under 21 U.S.C. § 355(j)(2)(B)(iv) and alleges, among other things, that in Teva USA's opinion, the '584 patent is "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva USA's product." Except as expressly admitted above, Teva denies the allegations in Paragraph 39.

40. Teva denies the allegations in Paragraph 40.

41. Teva denies the allegations in Paragraph 41.

42. Teva denies the allegations in Paragraph 42.

COUNT II

(INDUCEMENT OF INFRINGEMENT OF METHOD CLAIMS OF THE '584 PATENT UNDER 35 U.S.C. § 271(b))

43. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-42.

44. Teva denies the allegations in Paragraph 44.

45. Teva denies the allegations in Paragraph 45.

46. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 46.

47. Teva denies the allegations in Paragraph 47.

48. Teva denies the allegations in Paragraph 48.

49. Teva denies the allegations in Paragraph 49.

COUNT III

(CONTRIBUTORY INFRINGEMENT OF THE '584 PATENT UNDER 35 U.S.C. § 271(c))

50. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-49.

51. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 51.

52. Teva denies the allegations in Paragraph 52.

53. Teva denies the allegations in Paragraph 53.

54. Teva denies the allegations in Paragraph 54.

COUNT IV

(DIRECT INFRINGEMENT OF THE '043 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

55. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-54.

56. Teva admits that Teva USA filed ANDA No. 91-155 with the FDA under 21 U.S.C. § 355(j), seeking approval to market (i) combination Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, Eq. to 15 mg base/500 mg, and (ii) combination Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, Eq. to 15 mg base/850 mg. Except as expressly admitted above, Teva denies the allegations in Paragraph 56.

57. Upon information and belief, Teva USA admits that its combination pioglitazone and metformin drug products will be AB rated to Takeda's combination pioglitazone and metformin drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 57.

58. Teva admits that Teva USA's Notice Letter states that it submitted to the FDA ANDA No. 91-155 "which seeks approval to engage in the commercial manufacture, use, or sale of Pioglitazone Hydrochloride and Metformin Hydrochloride, Eq. to 15 mg base/500 mg and Eq. to 15 mg base/850 mg, prior to the expiration of the '584, '042, '043, and '090 patents." Except as expressly admitted above, Teva denies the allegations in Paragraph 58.

59. Teva admits that, by a letter dated April 14, 2009, Teva USA informed Takeda that Teva USA had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Teva admits the remaining allegations in Paragraph 59.

60. Teva admits that the Notice Letter provides Teva USA's notification of certification under 21 U.S.C. § 355(j)(2)(B)(iv) and alleges, among other things, that in Teva USA's opinion,

the '043 patent is "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva USA's product." Except as expressly admitted above, Teva denies the allegations in Paragraph 60.

61. Teva denies the allegations in Paragraph 61.

62. Teva denies the allegations in Paragraph 62.

63. Teva denies the allegations in Paragraph 63.

COUNT V

(INDUCEMENT OF INFRINGEMENT OF THE METHOD CLAIMS OF THE '043 PATENT UNDER 35 U.S.C. § 271(b))

64. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-63.

65. Teva denies the allegations in Paragraph 65.

66. Teva denies the allegations in Paragraph 66.

67. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 67.

68. Teva denies the allegations in Paragraph 68.

69. Teva denies the allegations in Paragraph 69.

70. Teva denies the allegations in Paragraph 70.

COUNT VI

(CONTRIBUTORY INFRINGEMENT OF THE '043 PATENT UNDER 35 U.S.C. § 271(c))

71. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-70.

72. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 72.

73. Teva denies the allegations in Paragraph 73.

74. Teva denies the allegations in Paragraph 74.

75. Teva denies the allegations in Paragraph 75.

COUNT VII

(DIRECT INFRINGEMENT OF THE '090 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

76. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-75.

77. Teva admits that Teva USA filed ANDA No. 91-155 with the FDA under 21 U.S.C. § 355(j), seeking approval to market (i) combination Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, Eq. to 15 mg base/500 mg, and (ii) combination Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, Eq. to 15 mg base/850 mg. Except as expressly admitted above, Teva denies the allegations in Paragraph 77.

78. Upon information and belief, Teva USA admits that its combination pioglitazone and metformin drug products will be AB rated to Takeda's combination pioglitazone and metformin drug products. Except as expressly admitted above, Teva denies the allegations in Paragraph 78.

79. Teva admits that Teva USA's Notice Letter states that it submitted to the FDA ANDA No. 91-155 "which seeks approval to engage in the commercial manufacture, use, or sale of Pioglitazone Hydrochloride and Metformin Hydrochloride, Eq. to 15 mg base/500 mg and Eq. to

15 mg base/850 mg, prior to the expiration of the '584, '042, '043, and '090 patents." Except as expressly admitted above, Teva denies the allegations in Paragraph 79.

80. Teva admits that, by a letter dated April 14, 2009, Teva USA informed Takeda that Teva USA had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Teva admits the remaining allegations in Paragraph 80.

81. Teva admits that the Notice Letter provides Teva USA's notification of certification under 21 U.S.C. § 355(j)(2)(B)(iv) and alleges, among other things, that in Teva USA's opinion, the '090 patent is "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva USA's product." Except as expressly admitted above, Teva denies the allegations in Paragraph 81.

82. Teva denies the allegations in Paragraph 82.

83. Teva denies the allegations in Paragraph 83.

84. Teva denies the allegations in Paragraph 84.

COUNT VIII

(INDUCEMENT OF INFRINGEMENT OF THE METHOD CLAIMS OF THE '090 PATENT UNDER 35 U.S.C. § 271(b))

85. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-84.

86. Teva denies the allegations in Paragraph 86.

87. Teva denies the allegations in Paragraph 87.

88. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 88.

89. Teva denies the allegations in Paragraph 89.

90. Teva denies the allegations in Paragraph 90.

91. Teva denies the allegations in Paragraph 91.

COUNT IX

(CONTRIBUTORY INFRINGEMENT OF THE '090 PATENT UNDER 35 U.S.C. § 271(c))

92. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-91.

93. Teva admits that the uses for which it seeks approval of ANDA No. 91-155 are set forth in the proposed labeling in that ANDA. Except as expressly admitted above, Teva denies the allegations in Paragraph 93.

94. Teva denies the allegations in Paragraph 94.

95. Teva denies the allegations in Paragraph 95.

96. Teva denies the allegations in Paragraph 96.

II. TEVA's ANDA No. 77-210

COUNT X

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '584 PATENT UNDER 35 U.S.C. § 271(b))

97. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-96.

98. Teva admits that Teva USA filed ANDA No. 77-210 with the FDA under 21 U.S.C. § 355(j), seeking approval to market (i) tablets comprising 15 mg of pioglitazone hydrochloride, (ii) tablets comprising 30 mg of pioglitazone hydrochloride, and (iii) tablets comprising 45 mg of pioglitazone hydrochloride. Except as expressly admitted above, Teva denies the allegations in Paragraph 98.

99. Teva denies the allegations in Paragraph 99.

100. Teva denies the allegations in Paragraph 100.

101. Teva denies the allegations in Paragraph 101.

102. Teva denies the allegations in Paragraph 102.

103. Teva denies the allegations in Paragraph 103.

104. Teva denies the allegations in Paragraph 104.

105. Teva denies the allegations in Paragraph 105.

COUNT XI

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '404 PATENT UNDER 35 U.S.C. § 271(b))

106. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-105.

107. Teva denies the allegations in Paragraph 107.

108. Teva denies the allegations in Paragraph 108.

109. Teva denies the allegations in Paragraph 109.

110. Teva denies the allegations in Paragraph 110.

111. Teva denies the allegations in Paragraph 111.

112. Teva denies the allegations in Paragraph 112.

113. Teva denies the allegations in Paragraph 113.

COUNT XII

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '043 PATENT UNDER 35 U.S.C. § 271(b))

114. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-113.

115. Teva denies the allegations in Paragraph 115.

116. Teva denies the allegations in Paragraph 116.

117. Teva denies the allegations in Paragraph 117.

118. Teva denies the allegations in Paragraph 118.

119. Teva denies the allegations in Paragraph 119.

120. Teva denies the allegations in Paragraph 120.

121. Teva denies the allegations in Paragraph 121.

COUNT XIII

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '090 PATENT UNDER 35 U.S.C. § 271(b))

122. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-121.

123. Teva denies the allegations in Paragraph 123.

124. Teva denies the allegations in Paragraph 124.

125. Teva denies the allegations in Paragraph 125.

126. Teva denies the allegations in Paragraph 126.

127. Teva denies the allegations in Paragraph 127.

128. Teva denies the allegations in Paragraph 128.

129. Teva denies the allegations in Paragraph 129.

COUNT XIV

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '205 PATENT UNDER 35 U.S.C. § 271(b))

130. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-129.

131. Teva denies the allegations in Paragraph 131.

132. Teva denies the allegations in Paragraph 132.

133. Teva denies the allegations in Paragraph 133.

134. Teva denies the allegations in Paragraph 134.

135. Teva denies the allegations in Paragraph 135.

136. Teva denies the allegations in Paragraph 136.

137. Teva denies the allegations in Paragraph 137.

COUNT XV

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '243 PATENT UNDER 35 U.S.C. § 271(b))

138. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-137.

139. Teva denies the allegations in Paragraph 139.

140. Teva denies the allegations in Paragraph 140.

141. Teva denies the allegations in Paragraph 141.

142. Teva denies the allegations in Paragraph 142.

143. Teva denies the allegations in Paragraph 143.

144. Teva denies the allegations in Paragraph 144.

145. Teva denies the allegations in Paragraph 145.

COUNT XVI

(INFRINGEMENT OF THE METHOD CLAIMS OF THE '640 PATENT UNDER 35 U.S.C. § 271(b))

146. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-145.

147. Teva denies the allegations in Paragraph 147.

148. Teva denies the allegations in Paragraph 148.

149. Teva denies the allegations in Paragraph 149.

150. Teva denies the allegations in Paragraph 150.

151. Teva denies the allegations in Paragraph 151.

152. Teva denies the allegations in Paragraph 152.

153. Teva denies the allegations in Paragraph 153.

Teva denies that Takeda is entitled to any relief requested in paragraphs (a) through (g) of its "prayer for relief."

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '584 patent.

SECOND AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '404 patent.

THIRD AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '043 patent.

FOURTH AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '090 patent.

FIFTH AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '205 patent.

SIXTH AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '243 patent.

SEVENTH AFFIRMATIVE DEFENSE

Teva has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '640 patent.

EIGHTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '584 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

NINTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '404 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

TENTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '043 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

ELEVENTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '090 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

TWELFTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '205 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRTEENTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '243 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

FOURTEENTH AFFIRMATIVE DEFENSE

Upon information and belief, the claims of the '640 patent are invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112. Without limiting the foregoing, upon further information and belief, the claims of the '640 patent are invalid due to nonstatutory double patenting.

FIFTEENTH AFFIRMATIVE DEFENSE

Takeda's claims for injunctive relief are barred because Takeda has an adequate remedy at law.

SIXTEENTH AFFIRMATIVE DEFENSE

Takeda's Complaint fails to state a claim upon which relief can be granted.

WHEREFORE, Teva hereby demands judgment dismissing Takeda's Complaint with prejudice, judgment for costs and fees of suit, and judgment for such other relief as the Court may deem just.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that this Court enter a Judgment and Order:

a) dismissing the Complaint, and each and every claim for relief contained therein, with prejudice;

b) declaring that Teva USA has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '584, '404, '043, '090, '205, '243, and '640 patents;

c) declaring that Teva Ltd. has not infringed, is not infringing, will not infringe, and will not contribute to or induce infringement of, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '584, '404, '043, '090, '205, '243, and '640 patents;

d) declaring the claims of the '584, '404, '043, '090, '205, '243, and '640 patents invalid for failure to comply with the requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112;

e) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Teva its attorneys' fees, costs, and expenses; and

f) granting Teva such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Teva hereby demands a jury trial on all issues so triable.

Dated: July 10, 2009

/s/ David P. Langlois
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